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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,348	11/01/2003	Michael O. Madsen	P-11706.00US	9656
54228	7590	02/22/2006	EXAMINER	
IPLM GROUP, P.A. POST OFFICE BOX 18455 MINNEAPOLIS, MN 55418			SZMAL, BRIAN SCOTT	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/698,348

Applicant(s)

MADSEN, MICHAEL O.

Examiner

Brian Szmal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2-2-04</u> . | 6) <input type="checkbox"/> Other: ____.  |

### ***Claim Objections***

1. Claims 7, 16, 22 and 27 are objected to because of the following informalities:

Claims 7, 16, 22 and 27 do not end in a ".". Furthermore, Claims 7, 16 and 22 disclose "said esophageal location", which lacks antecedent basis. Claim 7 also discloses "wherein identification occurs said predetermined distance", which is objected by the Examiner for the two following reasons: the phrase should read as "wherein identification occurs at said predetermined distance" to be grammatically correct; and it is unclear to the Examiner if the "identification" refers to the claimed identification of the upper boundary as claimed in Claim 1, or if it refers to measuring a parameter using the monitoring device. Claims 16, 22 and 27 also disclose "wherein identification occurs said predetermined distance", which is objected by the Examiner since it is unclear to the if the "identification" refers to the claimed identification of the upper boundary as claimed in Claims 10, 19 and 24, or if it refers to measuring a parameter using the monitoring device. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. Claims 1-5, 8-14, 17-20, 23-25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugrue et al (5,433,216) in view of Kilcoyne et al (6,285,897 B1).

Sugrue et al disclose a pressure measurement apparatus and method and further disclose passing a distal end of the catheter through an esophagus and a lower esophageal sphincter into a stomach of a patient; introducing a flow of gas having a constant pressure to a proximate end of the lumen of the esophageal catheter; measuring a lumen pressure of the gas in the lumen; pulling back the distal end of the catheter from the patient; noting an increase in the lumen pressure; noting a subsequent decrease in the lumen pressure; identifying an upper boundary of the lower esophageal sphincter based upon the decrease; determining a baseline for the lumen pressure before the pulling back step and wherein the increase in the lumen pressure is relative to the baseline; the distal end of the catheter is removed gradually; the increase is measured as the distal end of the catheter enters the lower esophageal sphincter; the decrease is measured as the distal end of the catheter passes an upper boundary of the lower esophageal sphincter; the pulling back step is accomplished in a series of incremental steps with pauses in between each of the incremental steps and wherein the measuring step is accomplished during the pauses; the gas comprises air; determining a baseline for the lumen pressure; determining a baseline for the lumen pressure before the pulling back step and wherein the increase in the lumen pressure is relative to the baseline; a source of gas having a constant pressure operatively coupled to a proximate end of the lumen; and pressure measurement means for measuring a

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lumen pressure of the gas in the lumen; whereby the distal end of the catheter may be removed from the patient while noting an increase in the lumen pressure relative to the baseline and subsequently noting a decrease in the lumen pressure thereby identifying an upper boundary of the lower esophageal sphincter upon the decrease; and means for determining a baseline for the lumen pressure before the pulling back step. See Column 13, lines 58-68; Column 14, lines 10-13; Column 16, lines 5-10 and 49-68; Column 18, lines 65-67; and Column 34, lines 66-68.

Even though Sugrue et al does not explicitly disclose the claimed steps for determining the position of the catheter in the esophagus, the disclosure in Column 16, lines 49-68, especially lines 61-68, inherently discloses the claimed steps.

Sugrue et al, however fail to disclose utilizing the lumen of the catheter for suction to aid in attaching a monitoring device to the esophagus; and a catheter, subsequently used for placing a monitoring device at the esophageal location in the patient, the catheter having a lumen, the catheter having a distal end capable of being passed through the esophagus and the lower esophageal sphincter into the stomach.

Kilcoyne et al disclose a remote physiological monitoring system and further disclose utilizing the lumen of the catheter for suction to aid in attaching a monitoring device to the esophagus; and a catheter, subsequently used for placing a monitoring device at the esophageal location in the patient, the catheter having a lumen, the catheter having a distal end capable of being passed through the esophagus and the lower esophageal sphincter into the stomach. See Column 7, lines 19-30; and Column 8, lines 14-23.

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Since both Sugrue et al and Kilcoyne et al disclose placing a catheter in the esophagus of a patient, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and apparatus of Sugrue et al to include the using the catheter to place a monitoring device at a desired site in the esophagus, as per the teachings of Kilcoyne et al, since it would allow a physician to place the monitoring device at an optimal site after determining the location of the lower esophageal sphincter.

4. Claims 6, 7, 15, 16, 21, 22, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugrue et al (5,433,216) and Kilcoyne et al (6,285,897 B1) as applied to claims 5, 14, 19 and 24 above, and further in view of Bombeck, IV (4,981,470).

Sugrue et al and Kilcoyne et al, as discussed above, disclose means for determining the location of the lower esophageal sphincter and placing a monitoring device, but fail to disclose measuring a predetermined distance from the upper boundary of the lower esophageal sphincter; and the esophageal location is a predetermined distance above the upper boundary of the lower esophageal sphincter.

Bombeck, IV discloses an esophageal catheter and further discloses measuring a predetermined distance from the upper boundary of the lower esophageal sphincter; and the esophageal location is a predetermined distance above the upper boundary of the lower esophageal sphincter. See Column 4, lines 38-50.

Since Sugrue et al, Kilcoyne et al and Bombeck, IV disclose esophageal catheters, it would have been obvious to one of ordinary skill in the art at the time the invention was

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made to modify the combination of Sugrue et al and Kilcoyne et al to include the measurement of a location in the esophagus above the lower esophageal sphincter, as per the teachings of Bombeck, IV, since the demarcations on the Bombeck, IV catheter would allow the physician to measure a location above the lower esophageal sphincter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmalec whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

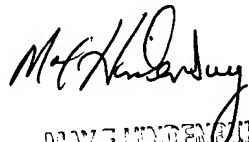
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BS



MARK H. ANDERSON  
SENIOR PATENT EXAMINER  
EBC CENTER 3736